EVOSS Dental Implant System User Manual

1-) EVO TI AND EVO X TYPE DENTAL IMPLANTS

Evoss Dental Implant System, mandibular and maxillary; It is used for treatment in single and partial edentulism. A tool specially designed to be surgically placed in or on the mandibular or maxillary bone in the form of a tool that provides support and attachment against the dislocation of the dental prosthesis. It is either passed through the gingiva by the dentist (a portion of the implant comes out directly from the gingiva to provide support) or is completely embedded under the gingiva (for removable denture support only).

• EVO - Tİ DENTAL IMPLANT: USED FOR PATIENTS WITH GOOD BONE LEVEL.

• EVO X TYPE DENTAL IMPLANT: IT IS USED FOR PATIENTS WITH LOW BONE LEVEL BIG. IT IS PREFERRED IF PATIENTS HAVE BONE OF THE REQUIRED DIAMETER.

Warning:

The information presented here is not sufficient for immediate application of the EVOSS® Dental Implant System. The user must be legally competent to perform a surgical operation and must have advanced training in the field of oral implantation and detailed information about the system components before use.

Legal Liability Statement:

Use of this product is the sole responsibility of the end user. No liability is assumed for any loss or damage that may occur if this product is misused or if this user manual is not followed. This system can only be used with original EVOSS® parts. Use of third party parts voids the warranty offered by EVOSS® and renders the product ineffective.

Copyright and Patent:

Logos of EVOSS® are protected patents and are only reserved for SC Medikal Urunleri Ltd. It is owned by the company. Any use of these signs is prohibited and is subject to investigation under Turkish and international law if used.

Education:

Dental implant treatment includes complex surgical and restorative procedures. Such applications should be carried out by dentists who have received the necessary training in this field. Inadequate training leads to surgical and prosthetic complications, resulting in implant and restoration failure.

Patient Population:

It is used in adult individuals who have completed their bone development.

Materiel:

ISO 5832-2 Unalloyed Titanium

Item Content:

Implants and contact parts are manufactured from ISO 5832-2 Grade 4 Unalloyed Titanium. EVOSS® surface microstructure has been roughened by large particle sandblasting and pickling (SLA) method to obtain optimum osseointegration Ra values.

EVOSS® Implants Indications for Use:

EVOSS® Dental Implants can be used to support and/or retain single-member, multi-member or all-arch fixed and/or removable dentures in partially or fully edentulous maxillary or mandibular arches. EVO X TYPE Implants can be placed surgically in two stages, EVO TI DENTAL IMPLANTS can be placed with a single stage surgical application.

Contraindications:

Although not limited; when general health is poor, serious internal medicine problems, uncontrolled diabetes, uncontrollable bleeding disorders, anticoagulant therapy, vascular disorders, insufficient wound healing, connective tissue disorders, chemo and radiation therapies, metabolic bone disease, uncontrolled hormone disorders, It is contraindicated in psychiatric disorders, drug and alcohol use, and allergy to titanium compounds.

Local Contraindications:

Local contraindications include, but are not limited to: situations where there is insufficient bone volume in terms of width and height, oral infections, periodontal disease status, parafunctional habits, severe dry mouth, poor oral hygiene, and situations where the patient is incompatible and inadequate in applying oral care.

Possible Side Effects:

- Infection
- Pain
- Neurosensory discomfort
- Mandibular fracture
- Hematoma formation
- Loss of vitality of the adjacent tooth
- air embolism
- Maxillary Sinus Perforation
- Lack of primary stability
- Opening the wound site
- Peri implanter mucositis
- Postoperative soft tissue complications
- Abscesses with suture residual origin

Apart from these, mechanical complications such as nail loosening, cracking, implant cracking, abutment loosening may also occur.

Packaging and Sterilization:

EVOSS® implants are packed sterile with cap screws. Products are disposable. Gamma radiation is used for sterilization of implants after packaging. Thanks to the sealed packaging, the implants are prevented from being affected by the external environment. Implants will be stored at a minimum temperature of 10°C and a maximum of 30°C and in conditions with minimum 0% and maximum 50% humidity. Sterilization is valid until the expiry date stated on the label on the package. Implants in deteriorated sterile packages should not be used. Contaminated implants cannot be resterilized. Reuse of implants can result in clinical failure and complications including, but not

limited to, infection, non-integration of implants, bone loss, and damage to adjacent structures. Try not to touch the implant surface by hand, as this may impair its surface properties.

Shelf Life: The expiry date is clearly marked on each implant package.

Treatment Planning:

Comprehensive patient examination, preoperative imaging, preoperative diagnosis and treatment planning should be done before implant treatment. Inadequate planning and evaluation can lead to implant complications or even implant failure..

Preparation of the Surgical Site:

Preparation of the implant site should be done with the surgical burs in the EVOSS® surgical set. The speed of the drilling process should be decided by the physician according to the degree of hardness of the bone. Drilling should be done under ample irrigation. Care should be taken to prevent the bone from getting too hot. The use of sharp surgical burs should be avoided as they may cause unnecessary trauma to the bone. The drill sequence table by implant diameter is available on the cover of the sets and it is recommended to follow it from there.

Surgical Placement of Implants:

Check the length and diameter of the implant on the product label. Affix the label (3 pieces) inside the package to the patient's file. Open the outer carton package and remove the inner sheath packaging. Open the transparent part of the sheath package and empty the sterile inner tube into the surgical area. The implant tube consists of two parts: 1- The upper cover with the closing screw, 2- The lower cover with the implant. Open the implant tube by lifting the lower cap. Use the implant carrier in the set to move the implant into the surgically prepared implant socket. It can be inserted using the torque disc included in the kit or the physiodispenser to place the implant. The cap screw must be inserted with a 1.25 mm hex screwdriver. Cover screws and healing caps should be torqued by hand.

Healing Process of EVOSS® Implants:

In general, implants should be left to heal for 2 to 4 months, depending on the patient's bone quality, type, and general health. Immediate and early loading can be achieved by choosing the right case and adhering to the immediate loading protocols accepted in the literature. If immediate loading is to be performed, the occlusion environment should be checked, if there is more than one implant, it should be splinted, and in cases of complete edentulism, at least 4 implants in the mandible and 6 implants in the maxilla should be connected to each other with prosthesis. Appropriate number, diameter and length of implants should be placed depending on the bone anatomy.

Post-Operative Care:

Close follow-up of the patient after surgery is very important. It is recommended to use appropriate mouthwashes and to provide good oral care and not to use tobacco products.

2-) EVOSS® Screw Off Indications:

The closure screws come out of the implant package used. It is used in two-stage implant surgical approaches where it is desired to close the implant and heal.

Material:

ISO 5832-3 Alloy Titanium

Indications:

EVOSS® abutments attach to EVOSS® implants with prosthetic screws, providing support and/or retention to prostheses.

Contraindications:

Contraindications are indicated above.

Possible Side Effects:

Possible side effects are mentioned above.

Placement:

Cover screws and healing caps are hand torqued using a 1.25 mm hex screwdriver.

Packaging and Sterilization:

The closure screws are packed in a sterile tube with the implant. If the package is intact, Sterilization is valid until the expiry date on the package.

Warnings:

Considering that different types of MRI devices are produced by various manufacturers and each instrument has different user-adjustable parameters, the net effect on the implant cannot be determined. Therefore, SC Medical recommends consultation with healthcare professionals and the MRI manufacturer on implant compatibility from use. In case of uncertainty, a possible practical test on the specific unit and proposed parameters may be considered.

Disposal:

Implants removed from the patient should not be re-implanted as the fatigue status of the device cannot be detected visually. These devices should be considered as biocontaminated and should be treated accordingly. Removed implants should be treated according to their biological hazards and disposed of in accordance with the country's legal regulations and hospital policies.

	It is sterilized by gamma irradiation and has a double sterile barrier system.
	Consult the instruction for use
	Lot number
	Product code number (Catalog number)
	Manufacturer name and address and production date
	Warning
	Production date
	It may break, handle it with care.
	Keep away from sunlight
	keep dry
	For single use, do not reuse
	Medical device
	Use within due time (expiration date)
	Do not re-sterile
	Do not use if the packaging is damaged.
	temperature limitation
	humidity limitation
	Unique device ID